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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

Dear Ms. Axelrad:

This is in regard to the application for patent term extension for U.S. Patent No. 6,462,058 (the '058 patent) filed March 26, 2009, and forwarded to FDA on April 29, 2009.

The Federal Circuit recently upheld the validity of a patent term extension for a patent claiming an enantiomer in light a previous approval of a racemate having the same chemical formula. In *Ortho-McNeil Pharm., Inc. v. Lupin Pharms., Inc.*, 603 F.3d 1377 (Fed. Cir. 2010), a generic pharmaceutical company was sued for patent infringement under the provisions of 35 U.S.C. § 271(e)(2) and defended against infringement by asserting that the USPTO improperly issued an extension of the term of a patent (U.S. Patent No. 5,053,407) which claimed the human drug product Levaquin® (levofloxacin) and hence the patent (extension) was invalid and could not be infringed. The basis for the challenge to the proprietary of the patent term extension was that the approval of Levaquin® did not represent the first permitted commercial marketing or use of the drug product as required by 35 U.S.C. § 156(a)(5)(A) because the racemate, Floxin® (ofloxacin), was approved before a single enantiomer of ofloxacin, Levaquin®. The USPTO maintains that a patent which claims an enantiomer, which was subject to regulatory review before FDA before its commercial marketing or use, is eligible for extension even if a racemate having the same chemical formula had been previously approved. That is, the approval of a racemate does not exhaust patent term extension for either an R or S enantiomer of the racemate. In upholding the validity of the patent term extension for Ortho-McNeil's Levaquin®, the court concluded that "the enantiomer [levofloxacin] is a different drug product from the racemate ofloxacin . . . ." *Id.* at. 1381.

Here, the '058 patent claims a specific crystal structure of dexlansoprazole and a pharmaceutical composition of dexlansoprazole. Dexlansoprazole, the subject of NDA No. 22-287 which was approved by FDA on January 20, 2009, is the active ingredient in the human drug product DEXILANT™. Lansoprazole is a racemate having the same chemical formula as dexlansoprazole and was approved by FDA on May 10, 1995. In accordance with the holding of *Ortho-McNeil Pharm., Inc. v Lupin Pharms., Inc.*, it is the position of the USPTO that the patent claiming a specific crystal structure of dexlansoprazole and a pharmaceutical composition of dexlansoprazole (DEXILANT™) is eligible for patent term extension since the approval of DEXILANT™ complies with the requirement of section 156(a)(5)(A). Thus, is it requested that the FDA make their determination on eligibility for U.S. Patent No. 6,462,058 in accordance with the decision articulated by the Federal Circuit in *Ortho-McNeil Pharm., Inc. v Lupin Pharms., Inc.*

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
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RE: DEXILANT® (dexlansoprazole)
Docket No.: FDA-2009-E-0238